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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ARBUTUS BIOPHARMA CORP. and GENEVANT SCIENCES GMBH, Plaintiffs, v. PFIZER INC. and BIONTECH SE, Defendants.	Civil Action No. 3:23-1876-ZNQ-TJB *Document Filed Electronically* Jury Trial Demanded

PLAINTIFFS' ANSWER TO DEFENDANTS' COUNTERCLAIMS

Arbutus Biopharma Corp. ("Arbutus") and Genevant Sciences GmbH ("Genevant") (collectively, "Plaintiffs") submit their Answer to Pfizer Inc.'s ("Pfizer") and BioNTech SE's ("BioNTech") (collectively, "Defendants" or "Counterclaimants") Counterclaims.

COUNTERCLAIMS

1. Counterclaimants on personal knowledge as to their own acts, and on information and belief as to all others based on their own and their attorneys' investigation, and without admitting the allegations of Plaintiffs other than those expressly admitted herein, bring the following Counterclaims against Arbutus and Genevant for declaratory judgment that United States Patent Nos. 9,504,651 (the "'651 Patent"); 8,492,359 (the "'359 Patent"); 11,141,378 (the "'378 Patent"); 11,298,320 (the "'320 Patent"); and 11,318,098 (the "'098 Patent") (collectively, the "Asserted Patents") are invalid and not infringed by Counterclaimants. Additionally, Counterclaimants bring the following Counterclaims that the '378 Patent, '320 Patent, and '098 Patent are unenforceable.

ANSWER: Plaintiffs lack sufficient knowledge as to Defendants' personal knowledge, acts, or beliefs to form a belief as to the truth of Defendants' allegations. Plaintiffs admit that Defendants purport to seek declaratory judgments of non-infringement and invalidity of the Asserted Patents, and unenforceability of the '378 Patent, '320 Patent, and '098 Patent. Plaintiffs deny the remaining allegations of paragraph 1.

2. Counterclaimants repeat and incorporate by reference each of the foregoing paragraphs of Defendants' Answer and Affirmative Defenses to the Complaint, as if fully set forth herein.

ANSWER: To the extent a response is required, Plaintiffs repeat and incorporate by reference each paragraph of their Complaint. Plaintiffs otherwise deny the allegations of paragraph 2.

THE PARTIES

3. Pfizer is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 66 Hudson Boulevard, New York, New York 10001.

ANSWER: Admitted on information and belief.

4. BioNTech is a corporation organized and existing under the laws of Germany with a principal place of business at An der Goldgrube 12, D-55131 Mainz, Germany.

ANSWER: Admitted on information and belief.

5. According to its Complaint (D.I. 1), Arbutus is a corporation organized and existing under the laws of Canada, with its principal place of business at 701 Veterans Circle, Warminster,

Pennsylvania 18974. According to its Complaint, Arbutus is the owner by assignment of the Asserted Patents.

ANSWER: Plaintiffs' Complaint speaks for itself.

6. According to its Complaint (D.I. 1), Genevant is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland. According to its Complaint, Genevant is the licensee to exclusive rights for the Asserted Patents to sublicense, practice, and sue for infringement in certain fields of use that allegedly include the vaccine application at issue in its Complaint.

ANSWER: Plaintiffs' Complaint speaks for itself.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 based on an actual controversy among the parties arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

ANSWER: Paragraph 7 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that this Court has subject matter jurisdiction over this action.

8. Personal jurisdiction over Arbutus and Genevant is proper because each has consented to the personal jurisdiction of the Court by commencing their action for patent infringement in this judicial district, as set forth in their Complaint.

ANSWER: Paragraph 8 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that they filed the Complaint and do not contest that they are subject to personal jurisdiction for purposes of this action.

9. Venue is proper in this judicial district based on the choice of forum by Arbutus and Genevant and under 28 U.S.C. § 1391(b)-(c).

ANSWER: Paragraph 9 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that this district is a proper venue for this action.

10. There is an actual justiciable controversy among the parties concerning non-infringement and invalidity of the Asserted Patents.

ANSWER: Paragraph 10 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that there is an actual justiciable controversy among the parties concerning non-infringement and invalidity of the Asserted Patents.

CASE AND CONTROVERSY

11. The '651 Patent, titled "Lipid Compositions for Nucleic Acid Delivery," states an issue date of November 29, 2016 and names as inventors Ian MacLachlan, Lloyd Jeffs, Lorne R. Palmer, and Cory Giesbrecht. Upon information and belief, a true and correct copy of the '651 Patent is attached to the Complaint as Exhibit A (D.I. 1-1).

ANSWER: Admitted.

12. The '359 Patent, titled "Lipid Formulations for Nucleic Acid Delivery," states an issue date of July 23, 2013 and names as inventors Edward Yaworski, Kieu Lam, Lloyd Jeffs, Lorne Palmer, and Ian MacLachlan. Upon information and belief, a true and correct copy of the '359 Patent is attached to the Complaint as Exhibit B (D.I. 1-2).

ANSWER: Admitted.

13. The '378 Patent, titled "Lipid Formulations for Nucleic Acid Delivery," states an issue date of October 12, 2021 and names as inventors Edward Yaworski, Kieu Lam, Lloyd Jeffs, Lorne Palmer, and Ian MacLachlan. Upon information and belief, a true and correct copy of the '378 Patent is attached to the Complaint as Exhibit C (D.I. 1-3).

ANSWER: Admitted.

14. The '320 Patent, titled "Liposomal Apparatus and Manufacturing Methods," states an issue date of April 12, 2022 and names as inventors Ian MacLachlan, Lloyd B. Jeffs, Lorne R. Palmer, and Cory Giesbrecht. Upon information and belief, a true and correct copy of the '320 Patent is attached to the Complaint as Exhibit D (D.I. 1-4).

ANSWER: Admitted.

15. The '098 Patent, titled "Liposomal Apparatus and Manufacturing Methods," states an issue date of May 3, 2022 and names as inventors Ian MacLachlan, Lloyd B. Jeffs, Lorne R. Palmer, and Cory Giesbrecht. Upon information and belief, a true and correct copy of the '098 Patent is attached to the Complaint as Exhibit E (D.I. 1-5).

ANSWER: Admitted.

16. Arbutus purports to be the owner and assignee of all Asserted Patents.

ANSWER: Plaintiffs' Complaint speaks for itself.

17. Genevant purports to be an exclusive licensee to all Asserted Patents.

ANSWER: Plaintiffs' Complaint speaks for itself.

18. An actual, substantial, and justifiable controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, exists between Counterclaimants and Counterclaim-Defendants.

ANSWER: Admitted.

19. Counterclaimants are entitled to a judicial determination and declaration that they have not infringed and are not infringing the Asserted Patents and that the Asserted Patents are invalid. Counterclaimants additionally seek a declaration that the '378 Patent, '320 Patent, and '098 Patent are unenforceable.

ANSWER: Paragraph 19 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Defendants purportedly seek a judicial determination and declaration that they have not infringed and are not infringing the Asserted Patents and that the Asserted Patents are invalid. Plaintiffs admit that Defendants purportedly seek a judicial determination and declaration that the '378 Patent, '320 Patent, and '098 Patent are unenforceable. Plaintiffs deny the remaining allegations of paragraph 19.

BACKGROUND ON COMIRNATY®

20. In December of 2019, it was discovered that an outbreak of pneumonia among people who had visited the Huanan Seafood Wholesale Market in Wuhan, China was caused by a novel coronavirus, eventually designated by the World Health Organization as SARS-CoV-2 with the disease it causes reclassified as Coronavirus disease 2019 ("COVID-19").

ANSWER: Plaintiffs admit that the disease caused by the SARS-CoV-2 virus is known as COVID-19. Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 20, and therefore deny them.

21. COVID-19 quickly spread around the world and tore through populations that were immunologically naïve, threatening the collapse of the healthcare system and the loss of life at scales not seen since the advent of modern medicine. What began first as small area lockdowns to prevent the transmission of disease and temporary stay-at-home orders eventually became society altering restrictions. Many saw that the only path out of the pandemic was the development of successful vaccines against the disease.

ANSWER: Plaintiffs admit that COVID-19 spread around the world, threatened healthcare systems, and resulted in loss of life. Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 21, and therefore deny them.

22. On January 10, 2020, the Chinese Center for Disease Control published the genetic sequence of SARS-CoV-2.

ANSWER: Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 22, and therefore deny them.

23. BioNTech scientists had been working in the field of mRNA technology since at least the founding of the company in 2008. BioNTech was working on messenger RNA ("mRNA")-based clinical vaccine candidates by the early- to mid-2010s. BioNTech was earning itself a reputation as an industry leader in mRNA technology.

ANSWER: Plaintiffs admit that BioNTech is involved in the field of mRNA technology. Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 23, and therefore deny them.

24. To combat the pandemic, BioNTech scientists set to work on developing a COVID-19 disease vaccine. BioNTech was able to do so by building on its existing development work and experience with mRNA-based clinical vaccine candidates. BioNTech eventually identified a product candidate—then known as BNT162—as a potential mRNA-based vaccine that would protect against COVID-19.

ANSWER: Plaintiffs admit that BioNTech worked on developing a COVID-19 vaccine and that its product candidate is known as BNT162. Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 24, and therefore deny them.

25. In March 2020, Pfizer and BioNTech began a collaborative effort focused on bringing a COVID-19 disease vaccine to market. The vaccine that ultimately emerged from this partnership was a novel mRNA vaccine now known as Comirnaty®.

ANSWER: Plaintiffs admit that the vaccine that ultimately emerged from Pfizer and BioNTech's effort is known as Comirnaty®. Plaintiffs lack sufficient knowledge or information

to form a belief as to the truth of the remaining allegations of paragraph 25, and therefore deny them.

26. Clinical trials of Pfizer/BioNTech vaccine candidates began in late April of 2020, with preliminary Phase 3 results demonstrating their safety and efficacy published in just over six months.

ANSWER: Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 26, and therefore deny them.

27. On November 20, 2020, Pfizer, on behalf of itself and BioNTech, submitted its clinical trial data as part of its Emergency Use Authorization ("EUA") request to the Food and Drug Administration ("FDA") for administering its mRNA vaccine to people 16 years of age and older.

ANSWER: Admitted.

28. On December 10, 2020, the FDA granted the first EUA for a COVID-19 vaccine to Pfizer and BioNTech's mRNA vaccine (now known as Comirnaty®) with vaccinations rolling out immediately thereafter, reflecting the fastest development of a vaccine in history.

ANSWER: Admitted.

29. The FDA provided Pfizer and BioNTech's vaccine with full approval on August 23, 2021.

ANSWER: Admitted.

30. Since being granted EUA, millions of doses of Comirnaty® have been administered worldwide, resulting in countless numbers of lives saved while easing the strain of an otherwise uncontrollable pandemic. During this same time, Arbutus and Genevant did not develop or sell any COVID-19 vaccine.

ANSWER: Plaintiffs admit that millions of doses of Comirnaty® have been administered worldwide since the EUA was granted, and that they have saved many lives and eased the strain of the pandemic. Plaintiffs admit that they have not sold a COVID-19 vaccine product since the EUA was granted, though Plaintiff's LNP technology is included in COVID-19 vaccines such as Comirnaty. Plaintiffs deny the remaining allegations of paragraph 30.

BIONTECH'S RELATIONSHIP WITH ACUITAS

31. Comirnaty® is an mRNA vaccine. For an mRNA vaccine to be effective, the mRNA needs to enter into the cells of the patient. However, mRNA typically breaks down quickly when injected into the body and cannot enter into a patient's cells on its own. An effective mRNA vaccine therefore also requires a delivery system that will protect the mRNA after injection into the patient and transport the mRNA into the patient's cells.

ANSWER: Admitted.

32. The need for a delivery system for a COVID-19 vaccine led BioNTech to partner with Acuitas Therapeutics, Inc. ("Acuitas") in the design of the COVID-19 vaccine lipid nanoparticle formulation. Upon information and belief, Acuitas had painstakingly engineered a microscopic sphere of fats called a lipid nanoparticle ("LNP") that can envelop and protect the mRNA. These LNPs allow the mRNA to cross the membrane of a human cell and then release the mRNA payload so it can be used to create the proteins that will in turn generate a protective immune response.

ANSWER: Plaintiffs admit that molecules known as LNPs can protect mRNA and allow mRNA to cross the membrane of a human cell and then release the mRNA payload. Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations in this paragraph, and therefore deny them.

33. Acuitas actively participated in the development of Comirnaty®. For example, during the development of Comirnaty®, Acuitas recommended using a lipid composition containing its proprietary lipids ALC-0315 and ALC-0159. Upon information and belief, this lipid composition had been shown to be effective in a prior clinical trial for a rabies vaccine. Acuitas also actively participated in the selection and design of the proportions of LNP components.

ANSWER: Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph, and therefore deny them.

34. BioNTech licensed ALC-0315 and ALC-0159 (otherwise known by their IUPAC names [4-hydroxybutyl)azanediyl]di(hexane-6,1-diyl) bis(2-hexyldecanoate), and alpha-[2-(ditetradecylamino)-2-oxoethyl]-omega-methoxy-poly(oxy-1,2-ethanediyl), respectively) from Acuitas.

ANSWER: Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph, and therefore deny them.

ONGOING LITIGATION BETWEEN PLAINTIFFS AND ACUITAS

35. On November 23, 2020, days after Pfizer and BioNTech's successful Phase 3 clinical-trial results for Comirnaty® were made public, Arbutus and Genevant sent a demand letter to Pfizer, copying BioNTech, stating: "We believe and notify you as contemplated by 35 U.S.C. § 287(a) that the manufacture, importation, offer for sale, sale, and/or use of your COVID-19 vaccine may infringe Arbutus patents, including at least U.S. Patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,006,417, 9,404,127, 9,364,435, 9,504,651, and 9,518,272."

ANSWER: Plaintiffs admit that on November 23, 2020, Plaintiffs sent a letter to Pfizer with copy to BioNTech. That letter speaks for itself.

36. On October 12, 2021, Genevant and Arbutus wrote another letter to Pfizer, copying BioNTech, stating: "[W]e believe, and notify Pfizer and BioNTech under 35 U.S.C. § 287(a), that the manufacture, importation, offer for sale, sale, and/or use of the Pfizer-BioNTech COVID-19 vaccine Comirnaty® may infringe Arbutus U.S. Patent No. 11,141,378, in addition to at least the Arbutus patents that were identified in our November 23, 2020 letter."

ANSWER: Plaintiffs admit that on October 12, 2021, Plaintiffs sent a letter to Pfizer with copy to BioNTech. That letter speaks for itself.

37. Genevant and Arbutus identified three of the five patents at issue in this litigation in their November 23, 2020 and October 12, 2021 letters, *i.e.* the '359, '651, and '378 patents. The remaining two patents asserted by Genevant and Arbutus in this litigation had not issued at that time.

ANSWER: Plaintiffs admit that they sent letters on November 23, 2020 and October 12, 2021. Those letters speak for themselves. Plaintiffs admit that the '320 patent and the '098 patent had not issued at the time of the letters.

38. On March 18, 2022, Acuitas filed an action against Arbutus and Genevant in the U.S. District Court for the Southern District of New York on March 18, 2022, seeking a declaratory judgement that the identified patents were invalid and not infringed. *Acuitas Therapeutics Inc. v. Genevant Sciences GmbH and Arbutus Biopharma Corp.*, No. 22-2229 (S.D.N.Y. Mar. 18, 2022), D.I. 1.

ANSWER: Admitted.

39. On June 3, 2022, Genevant sent email correspondence to BioNTech, copying Pfizer, stating: "We are sending this email to memorialize our disclosure made on [a previous] call of two additional Arbutus patents, U.S. Patent Nos. 11,298,320 and 11,318,098, which we believe, like the patents specified in our November 23, 2020 and October 12, 2021 letters sent to Pfizer and

BioNTech, may be infringed by the manufacture, importation, offer to sale, sale, and/or use of the Pfizer-BioNTech COVID-19 vaccine Comirnaty."

ANSWER: Plaintiffs admit that on June 3, 2022, Genevant sent an email to BioNTech with copy to Pfizer. That email speaks for itself.

40. Following this email correspondence and in response to Acuitas's declaratory judgment action, Arbutus and Genevant filed a motion to dismiss, asserting that there was not in fact a case or controversy. *Acuitas Therapeutics Inc. v. Genevant Sciences GmbH and Arbutus Biopharma Corp.*, No. 22-2229 (S.D.N.Y. Oct. 4, 2022), D.I. 44.

ANSWER: Admitted.

41. In support of their motion to dismiss, Arbutus and Genevant argued that they had not, in fact, ever threatened BioNTech or Pfizer with patent infringement, stating: "The letters state that Pfizer and BNT 'may' infringe Defendants' patents, which is far short of the types of accusations of infringement that the Federal Circuit has found to create an actual controversy as to infringement." *Id.* at 23.

ANSWER: Plaintiffs admit that on October 4, 2022, Plaintiffs filed a motion to dismiss in *Acuitas Therapeutics Inc. v. Genevant Sciences GmbH and Arbutus Biopharma Corp.*, No. 22-cv-2229 (S.D.N.Y.). That motion speaks for itself.

42. After sending the November 23, 2020 letter, October 12, 2021 letter, and June 3, 2022 email correspondence, Arbutus and Genevant ceased communications with BioNTech and Pfizer, and ten months later, filed their instant patent infringement action in the District of New Jersey. Upon information and belief, Arbutus and Genevant have no reasonable explanation for why they decided to file suit in this district on April 4, 2023, after previously contending that they had not threatened BioNTech or Pfizer with patent infringement.

ANSWER: Plaintiffs admit that they filed their Complaint on April 4, 2023. Plaintiffs admit that they sent letters on November 23, 2020 and on October 12, 2021 to Pfizer with copy to BioNTech. Plaintiffs admit that Genevant sent an email on June 3, 2022 to BioNTech with copy to Pfizer. Plaintiffs deny the remaining allegations of paragraph 42.

43. Arbutus and Genevant's motion to dismiss in the Southern District of New York was fully briefed as of November 16, 2022. The Southern District of New York court has not ruled on the motion as of the date of this filing.

ANSWER: Admitted.

44. In their Complaint, Arbutus and Genevant did not identify Acuitas by name. For example, Arbutus and Genevant did not identify the lipids in Comirnaty® by their commonly known Acuitas trade names of ALC-0315 and ALC-0159, but instead only used their lengthy chemical names.

ANSWER: Plaintiffs admit that their Complaint did not identify Acuitas and that the Complaint referred to the lipids in Comirnaty® using their chemical names. Plaintiffs deny the remaining allegations of paragraph 44.

ARBUTUS AND GENEVENT IMPROPERLY SEEK TO PROFIT FROM PFIZER AND BIONTECH'S COMIRNATY® COVID-19 VACCINE

45. On information and belief, Protiva Biotherapeutics Ltd. ("Protiva") was founded in 2000 by Ian MacLachlan, a named inventor on all Asserted Patents.

ANSWER: Plaintiffs admit that Ian MacLachlan co-founded Protiva in 2000 and that he is a named inventor on all Asserted Patents.

46. On information and belief, Protiva combined with Tekmira Pharmaceuticals Corp. ("Tekmira") in 2008.

ANSWER: Admitted.

47. On information and belief, Tekmira's founders left Tekmira and eventually formed a new venture, known today as Acuitas, to develop LNP technology. Specifically, Acuitas sought to develop lipid carriers for delivering mRNA, whereas Tekmira sought to develop lipid carriers for delivering small interfering RNA ("siRNA").

ANSWER: Plaintiffs admit that certain of Tekmira's founders had their employment terminated and that they then formed a new venture, known today as Acuitas. Plaintiffs lack sufficient knowledge or information to form a belief as to the truth of the remining allegations of paragraph 47, and therefore deny them.

48. On information and belief, Tekmira changed its corporate name to Arbutus Biopharma Corp. in 2015.

ANSWER: Admitted.

49. Arbutus and Genevant, which purports to be an exclusive licensee of all Asserted Patents, have made belated efforts to improperly expand the Arbutus patent portfolio so that they can try to capitalize on Pfizer and BioNTech's success.

ANSWER: Denied.

50. Arbutus and Genevant now seek to profit not from technology Arbutus or its predecessors invented, but rather from improperly contorting the claims of Arbutus's recent patent applications to what they allege covers Comirnaty®.

ANSWER: Denied.

51. Arbutus or Genevant do not report having made and used an LNP encapsulating mRNA in any of the Asserted Patents.

ANSWER: The Asserted Patents speak for themselves.

52. Arbutus and Genevant's alleged lipid technology is not a COVID-19 vaccine.

ANSWER: The allegations of paragraph 52 are too vague and ambiguous to permit a response and are therefore denied.

53. Arbutus and Genevant's alleged lipid technology has never been included in a COVID-19 vaccine.

ANSWER: Denied.

PROSECUTION HISTORY OF U.S. PAT. NO. 11,141,378 FAMILY

54. On April 15, 2008, Protiva filed a provisional application, U.S. Provisional Patent Application No. 61/045,228 (the "'228 Application"), with claims that state "[a] nucleic acid-lipid particle comprising: (a) a nucleic acid; [and] (b) a cationic lipid comprising **from about 50 mol % to about 85 mol %** of the total lipid present in the particle." (Emphasis added). In the specification, all examples encapsulating a nucleic acid use only siRNA molecules as the nucleic acid.

ANSWER: Plaintiffs admit that Protiva filed the '228 Application on April 15, 2008. The '228 Application speaks for itself.

55. On April 15, 2009, Protiva filed the first non-provisional patent application in this family, U.S. Patent Application No. 12/424,367 (the "'367 Application"), which originally claimed after a preliminary amendment "[a] nucleic acid-lipid particle comprising: (a) a nucleic acid; [and] (b) a cationic lipid comprising **from about 50 mol % to about 65 mol %** of the total lipid present in the particle." (Emphasis added). Again, all examples in the specification encapsulating a nucleic acid use only siRNA molecules as the nucleic acid.

ANSWER: Plaintiffs admit that Protiva filed the '367 Application on April 15, 2009. The '367 Application speaks for itself.

56. During prosecution of the '367 Application, the Examiner issued non-final rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) for all pending claims as anticipated and obvious in light of another Protiva patent application, U.S. Patent Publication No. 2006/0008910 (the "'910 Publication"). In particular, the Examiner issued a second non-final rejection under §§ 102(b) and 103(a) on May 12, 2011 for all pending claims, finding that "the relative amounts of components read on a broad range of amounts because of the term 'comprising about,'" which "could embrace an amount +/- 10, 20, 30 mol % of a lipid component." The Examiner also found that "the term 'comprising from about' . . . embrace[d] a broad range of SNALP formulations."

ANSWER: The prosecution history of the '367 Application speaks for itself.

57. Following this rejection, Protiva and the Examiner conducted a series of telephonic interviews in which Protiva proposed removing the word "about" to support that the claimed ranges were not anticipated by the '910 Publication. As a result, the Examiner agreed to withdraw the rejections under §§ 102(b) and 103(a). Shortly after the telephonic interviews, Protiva amended the claims on August 11, 2011 to remove the word "about" so that the patent required "a cationic lipid comprising **from 50 mol % to 65 mol %** of the total lipid present in the particle." (Emphasis added).

ANSWER: The prosecution history of the '367 Application speaks for itself.

58. On September 12, 2011, the Examiner issued a Notice of Allowance and the '367 Application issued as U.S. Pat. No. 8,058,069 (the "'069 Patent") on November 15, 2011.

ANSWER: Admitted.

59. From this family, Protiva was issued three additional patents—U.S. Pat. Nos. 8,492,359 (the "'359 Patent"), 8,822,668 (the "'668 Patent"), and 9,364,435 (the "'435 Patent"). Each of those patents continue to exclude the word "about" from the claims reciting molar lipid ratios for the cationic lipid.

ANSWER: Plaintiffs admit that Protiva was issued the '359 Patent, the '668 Patent, and the '435 Patent. Those patents speak for themselves.

60. On December 11, 2020, the FDA issued a publicly available EUA for emergency use of Pfizer and BioNTech's mRNA vaccine (now known as Comirnaty®). The letter of authorization to Pfizer provides the lipids and their amounts per dose for the LNP used in Comirnaty®.

ANSWER: Admitted.

61. On April 12, 2021, four months after the lipids and their amounts per dose for Comirnaty® were made public and nearly thirteen years after Protiva filed the original provisional application, Arbutus (purportedly assigned rights to the patent family) filed a new patent application in this family, U.S. Patent Application No. 17/227,802 (the "'802 Application").

ANSWER: Plaintiffs admit that the '802 Application was filed on April 12, 2021 and that Arbutus is the assignee of the rights to the patent family. Plaintiffs admit that the '228 Application (the "original provisional application") was filed on April 15, 2008. The '802 Application and the '228 Application speak for themselves. Plaintiffs deny the remaining allegations of paragraph 61.

62. The '802 Application purports to claim "[a] nucleic acid-lipid particle consisting essentially of: (a) an RNA; [and] (b) a cationic lipid." The claims of the '802 Application do not expressly recite any numerical values for a molar lipid ratio of the cationic lipid, let alone the "**from 50 mol % to 65 mol %**" or "**from 50 mol % to 85 mol %**" values that were included in the previously issued patents and alleged to be a basis for patentability.

ANSWER: The '802 Application, the prosecution history of the '802 Application, and the previously issued patents speak for themselves. Plaintiffs deny the remaining allegations of paragraph 62.

63. Despite not providing an express numerical value limitation as to the molar lipid ratio of the cationic lipid, Claim 1 of the '802 Application does provide an express limitation as to the molar lipid ratio values for all other lipids of the nucleic acid-lipid particle. Upon information and belief, this was a deliberate patent prosecution strategy to make less apparent to the U.S. Patent and Trademark Office that Arbutus and Genevant wished to claim molar lipid ratios of cationic lipid that were not supported by the patent specification and would, if not included, conflict with their prior positions as to a basis for patentability. For example, Claim 1 as originally filed reads:

> 1. A nucleic acid-lipid particle consisting essentially of: (a) an RNA; (b) a cationic lipid having a protonatable tertiary amine; (c) a mixture of a phospholipid and cholesterol of from 30 mol % to 55 mol % of the total lipid present in the particle; and (d) a polyethyleneglycol (PEG)-lipid conjugate consisting of from 0.1 mol % to 2 mol % of the total lipid present in the particle.

ANSWER: The '802 Application and the prosecution history of the '802 Application speak for themselves. Plaintiffs deny the remaining allegations of paragraph 63.

64. In the specification for the '802 Application, all examples encapsulating an RNA use only siRNA molecules as the RNA.

ANSWER: The '802 Application speaks for itself.

65. On October 12, 2021, the '802 Application issued as the '378 Patent.

ANSWER: Admitted.

66. Arbutus and Genevant sent a letter to Pfizer, copying BioNTech, accusing Pfizer and BioNTech that they may infringe the '378 Patent—despite knowing that the LNP used in Comirnaty® is outside the scope of the claims of the '378 Patent and outside the scope of what Protiva allegedly invented.

ANSWER: Plaintiffs admit that they sent a letter to Pfizer with copy to BioNTech on October 12, 2021. That letter speaks for itself. Plaintiffs deny the remaining allegations of paragraph 66.

67. Arbutus and Genevant have initiated this lawsuit to enforce the '378 Patent against Pfizer and BioNTech seeking damages despite knowing that the LNP used in Comirnaty® is outside the scope of the claims of the '378 Patent and outside the scope of what Protiva allegedly invented.

ANSWER: Plaintiffs admit to initiating this lawsuit, which includes assertion of the '378 Patent. Plaintiffs admit that they are seeking damages in this lawsuit. Plaintiffs deny the remaining allegations of paragraph 67.

PROSECUTION HISTORY OF U.S. PAT. NOS. 11,298,320 AND 11,318,098 FAMILY

68. On June 28, 2002, Protiva filed a provisional application, U.S. Provisional Patent Application No. 60/392,887 (the "'887 Application"), with claims reciting processes and apparatuses for producing a liposome by mixing an organic lipid solution with an aqueous solution by introducing them into a mixing environment. In the specification, all figures and examples in which the organic lipid solution and the aqueous solution are mixed involve introducing them into the mixing environment at the same flow rate.

ANSWER: Plaintiffs admit that Protiva filed the '887 Application on June 28, 2002. The '887 Application speaks for itself. Plaintiffs deny the remaining allegations of paragraph 68.

69. In the following non-provisional patent applications and any patents that issued therefrom directed to processes and apparatuses in this family, all claims directed to flow rates required mixing an organic lipid solution with an aqueous solution by introducing them into a mixing environment at "substantially equal flow rates" or "about equal flow rates."

ANSWER: U.S. Patent Nos. 7,901,708, 8,329,070, 9,492,386, and U.S. Patent Application Nos. 17/330,209 and 17/329,755 speak for themselves.

70. The Patent and Trademark Office issued three patents to Protiva: U.S. Pat. Nos. 7,901,708 (the "'708 Patent"), 8,329,070 (the "'070 Patent"), and 9,492,386 (the "'386 Patent"). Each patent claims mixing at "about equal flow rates."

ANSWER: Plaintiffs admit that the U.S. Patent and Trademark Office issued the '708 Patent, the '070 Patent, and the '386 Patent to Protiva. Those patents speak for themselves.

71. On March 31, 2021, CNN aired an interview with Pfizer's President of Global Supply as he gave a tour of a Pfizer production facility, during which the below image of a "T-mixer" was shown.

ANSWER: Admitted.

72. In their Complaint, Arbutus and Genevant characterize this image as demonstrating the T-mixer as "a mixing chamber configured to create opposing flows of the aqueous (blue) and lipid (yellow) solutions at about 180° relative to each other and **at different flow rates relative to each other**." (Emphasis added).

ANSWER: Admitted.

73. On May 25, 2021, less than two months after the CNN interview aired and almost two decades after Protiva filed the provisional application, Arbutus filed new patent applications in this family, U.S. Patent Application No. 17/330,209 (the "'209 Application") and U.S. Patent Application No. 17/329,755 (the "'755 Application").

ANSWER: Plaintiffs admit that the '209 Application and '755 Application were filed on May 25, 2021. Plaintiffs deny any remaining allegations of paragraph 73.

74. The '209 Application and the '755 Application are the first applications in this family which recite claims for mixing solutions at "different flow rates relative to each other."

ANSWER: The '209 Application, '755 Application, and the other applications in the same family speak for themselves.

75. In the specifications of the '209 Application and the '755 Application, all figures and examples in which the organic lipid solution and the aqueous solution are mixed involve introducing them into the mixing environment at the same flow rate.

ANSWER: The '209 Application and '755 Application speak for themselves. Plaintiffs deny the remaining allegations of paragraph 75.

76. On April 12, 2022, the '209 Application issued as the '320 Patent.

ANSWER: Admitted.

77. On May 3, 2022, the '755 Application issued as the '098 Patent.

ANSWER: Admitted.

78. Genevant sent email correspondence to BioNTech, copying Pfizer, stating that the '320 and '098 Patents "may be infringed" by BioNTech and Pfizer—despite knowing that the manufacturing process used for Comirnaty® is outside the scope of the claims of those patents and outside the scope of what Protiva allegedly invented.

ANSWER: Plaintiffs admit that Genevant sent an email discussing the '320 and '098 Patents to BioNTech with copy to Pfizer on June 3, 2022. That email speaks for itself. Plaintiffs deny the remaining allegations of paragraph 78.

79. Arbutus and Genevant have initiated this lawsuit to enforce the '320 Patent and '098 Patent against Pfizer and BioNTech seeking damages despite knowing that the manufacturing process used for Comirnaty® is outside the scope of the claims of the '320 Patent and '098 Patent and outside the scope of what Protiva allegedly invented.

ANSWER: Plaintiffs admit to initiating this lawsuit, which includes assertion of the '320 Patent and '098 Patent. Plaintiffs admit that they are seeking damages in this lawsuit. Plaintiffs deny the remaining allegations of paragraph 79.

COUNT I – DECLARATION OF NON-INFRINGEMENT ('651 PATENT)

80. Counterclaimants incorporate by reference paragraphs 1 through 79 of their Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to paragraphs 1 through 79.

81. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '651 Patent.

ANSWER: Paragraph 81 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Defendants purport to bring this action under the Patent Laws of the United States and the Declaratory Judgement Act. Plaintiffs admit

that there is a case of actual controversy between Plaintiffs and Defendants regarding infringement of the '651 Patent.

82. Arbutus and Genevant have accused Counterclaimants of activities that they claim infringe the '651 Patent.

ANSWER: Admitted.

83. Counterclaimants do not and have not infringed, either directly or indirectly, any claim of the '651 Patent.

ANSWER: Denied.

84. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the '651 Patent.

ANSWER: Denied.

85. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

ANSWER: Denied.

COUNT II – DECLARATION OF NON-INFRINGEMENT ('359 PATENT)

86. Counterclaimants incorporate by reference paragraphs 1 through 85 of their Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to paragraphs 1 through 85.

87. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '359 Patent.

ANSWER: Paragraph 87 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Defendants purport to bring this action under the Patent Laws of the United States and the Declaratory Judgement Act. Plaintiffs admit that there is a case of actual controversy between Plaintiffs and Defendants regarding infringement of the '359 Patent.

88. Arbutus and Genevant have accused Counterclaimants of activities that they claim infringe the '359 Patent.

ANSWER: Admitted.

89. Counterclaimants do not and have not infringed, either directly or indirectly, any claim of the '359 Patent.

ANSWER: Denied.

90. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the '359 Patent.

ANSWER: Denied.

91. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

ANSWER: Denied.

COUNT III – DECLARATION OF NON-INFRINGEMENT ('378 PATENT)

92. Counterclaimants incorporate by reference paragraphs 1 through 91 of their Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to paragraphs 1 through 91.

93. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '378 Patent.

ANSWER: Paragraph 93 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Defendants purport to bring this action under the Patent Laws of the United States and the Declaratory Judgement Act. Plaintiffs admit that there is a case of actual controversy between Plaintiffs and Defendants regarding infringement of the '378 Patent.

94. Arbutus and Genevant have accused Counterclaimants of activities that they claim infringe the '378 Patent.

ANSWER: Admitted.

95. Counterclaimants do not and have not infringed, either directly or indirectly, any claim of the '378 Patent.

ANSWER: Denied.

96. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the '378 Patent.

ANSWER: Denied.

97. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

ANSWER: Denied.

COUNT IV – DECLARATION OF NON-INFRINGEMENT ('320 PATENT)

98. Counterclaimants incorporate by reference paragraphs 1 through 97 of their Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to paragraphs 1 through 97.

99. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '320 Patent.

ANSWER: Paragraph 99 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Defendants purport to bring this action under the Patent Laws of the United States and the Declaratory Judgement Act. Plaintiffs admit that there is a case of actual controversy between Plaintiffs and Defendants regarding infringement of the '320 Patent.

100. Arbutus and Genevant have accused Counterclaimants of activities that they claim infringe the '320 Patent.

ANSWER: Admitted.

101. Counterclaimants do not and have not infringed, either directly or indirectly, any claim of the '320 Patent.

ANSWER: Denied.

102. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the '320 Patent.

ANSWER: Denied.

103. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

ANSWER: Denied.

COUNT V – DECLARATION OF NON-INFRINGEMENT ('098 PATENT)

104. Counterclaimants incorporate by reference paragraphs 1 through 103 of their Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to paragraphs 1 through 103.

105. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '098 Patent.

ANSWER: Paragraph 105 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Defendants purport to bring this action under the Patent Laws of the United States and the Declaratory Judgement Act. Plaintiffs admit that there is a case of actual controversy between Plaintiffs and Defendants regarding infringement of the '098 Patent.

106. Arbutus and Genevant have accused Counterclaimants of activities that they claim infringe the '098 Patent.

ANSWER: Admitted.

107. Counterclaimants do not and have not infringed, either directly or indirectly, any claim of the '098 Patent.

ANSWER: Denied.

108. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the '098 Patent.

ANSWER: Denied.

109. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

ANSWER: Denied.

COUNT VI – DECLARATION OF INVALIDITY ('651 PATENT)

110. Counterclaimants incorporate by reference paragraphs 1 through 109 of their Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to paragraphs 1 through 109.

111. The claims of the '651 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

ANSWER: Denied.

112. Counterclaimants are entitled to a declaratory judgment from this Court that the '651 Patent is invalid.

ANSWER: Denied.

COUNT VII – DECLARATION OF INVALIDITY ('359 PATENT)

113. Counterclaimants incorporate by reference paragraphs 1 through 112 of their Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to paragraphs 1 through 112.

114. The claims of the '359 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

ANSWER: Denied.

115. Counterclaimants are entitled to a declaratory judgment from this Court that the '359 Patent is invalid.

ANSWER: Denied.

COUNT VIII – DECLARATION OF INVALIDITY ('378 PATENT)

116. Counterclaimants incorporate by reference paragraphs 1 through 115 of their Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to paragraphs 1 through 115.

117. The claims of the '378 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

ANSWER: Denied.

118. Counterclaimants are entitled to a declaratory judgment from this Court that the '378 Patent is invalid.

ANSWER: Denied.

COUNT IX – DECLARATION OF INVALIDITY ('320 PATENT)

119. Counterclaimants incorporate by reference paragraphs 1 through 118 of their Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to paragraphs 1 through 118.

120. The claims of the '320 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

ANSWER: Denied.

121. Counterclaimants are entitled to a declaratory judgment from this Court that the '320 Patent is invalid.

ANSWER: Denied.

COUNT X – DECLARATION OF INVALIDITY ('098 PATENT)

122. Counterclaimants incorporate by reference paragraphs 1 through 121 of their Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to paragraphs 1 through 121.

123. The claims of the '098 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

ANSWER: Denied.

124. Counterclaimants are entitled to a declaratory judgment from this Court that the '098 Patent is invalid.

ANSWER: Denied.

COUNT XI – DECLARATION OF PATENT MISUSE ('378 PATENT)

125. Counterclaimants incorporate by reference paragraphs 1 through 124 of their Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to paragraphs 1 through 124.

126. Arbutus and Genevant have sought to enforce and/or license the '378 Patent for products and acts they know are outside the claims of the '378 Patent.

ANSWER: Denied.

127. For any claims directed to "[a] nucleic acid-lipid particle comprising . . . a cationic lipid" within a range of molar ratios of the total lipid present in the particle, all family members of the '378 Patent family prior to the filing of the application that resulted in the '378 Patent require a cationic lipid comprising "from 50 mol % to 65 mol %" or "from 50 mol % to 85 mol %" of the total lipid present in the particle.

ANSWER: The '378 Patent and other patents and applications in the '378 Patent family speak for themselves.

128. All embodiments encapsulating an RNA in the '378 Patent disclose only siRNA molecules as the RNA, unlike the LNPs used in Comirnaty®.

ANSWER: The '378 Patent speaks for itself. Plaintiffs deny the remaining allegations in paragraph 128.

129. Arbutus only began prosecuting the claims of the '378 Patent, directed to a cationic lipid without any express limitation as to its molar ratio, after the lipid composition of Comirnaty® was published and years after the alleged priority date of the '378 Patent.

ANSWER: Plaintiffs admit that the '802 Application was filed on April 12, 2021. Plaintiffs deny the remaining allegations of paragraph 129.

130. There is no support for the claims of the '378 Patent in its specification.

ANSWER: Denied.

131. Arbutus's and Genevant's conduct in seeking to license and enforce the '378 Patent against products and acts they know to be outside the scope of the claims of the '378 Patent and outside the scope of what was actually invented is an attempt to seek an improper economic benefit.

ANSWER: Denied.

132. Arbutus and Genevant have engaged in a course of conduct that seeks to broaden the scope of the '378 Patent with anticompetitive effect.

ANSWER: Denied.

133. Arbutus's and Genevant's misuse of the '378 Patent renders it unenforceable.

ANSWER: Denied.

COUNT XII – DECLARATION OF PATENT MISUSE ('320 PATENT)

134. Counterclaimants incorporate by reference paragraphs 1 through 133 of their Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to paragraphs 1 through 133.

135. Arbutus and Genevant have sought to enforce and/or license the '320 Patent for products and acts they know are outside the claims of the '320 Patent.

ANSWER: Denied.

136. For any claims directed to flow rates, all family members of the '320 Patent family prior to the filing of the application that resulted in the '320 Patent require mixing an organic lipid solution with an aqueous solution by introducing them into a mixing environment at "substantially equal flow rates" or "about equal flow rates."

ANSWER: The '320 Patent and all patents and patent applications in the '320 Patent family speak for themselves. Plaintiffs deny the remaining allegations in paragraph 136.

137. All Figures in the '320 Patent illustrating flow in the "T-connector" are described as disclosing flow rates that are "substantially equivalent for both lipid and aqueous solution flows."

ANSWER: The '320 Patent speaks for itself. Plaintiffs deny the remaining allegations in paragraph 137.

138. Arbutus only began prosecuting the claims of the '320 Patent, directed to an apparatus for producing a lipid vesicle by mixing an organic lipid solution with an aqueous solution by introducing them into a mixing environment at "different flow rates relative to each other," after CNN aired the interview during which an image of a T-mixer was shown and years after the alleged priority date of the '320 Patent.

ANSWER: Plaintiffs admit that the '209 Application was filed on May 25, 2021. Plaintiffs deny the remaining allegations of paragraph 138.

139. There is no support for the claims of the '320 Patent in its specification.

ANSWER: Denied.

140. Arbutus's and Genevant's conduct in seeking to license and enforce the '320 Patent against products and acts they know to be outside the scope of the claims of the '320 Patent and outside the scope of what was actually invented is an attempt to seek an improper economic benefit.

ANSWER: Denied.

141. Arbutus and Genevant have engaged in a course of conduct that seeks to broaden the scope of the '320 Patent with anticompetitive effect.

ANSWER: Denied.

142. Arbutus's and Genevant's misuse of the '320 Patent renders it unenforceable.

ANSWER: Denied.

COUNT XIII – DECLARATION OF PATENT MISUSE ('098 PATENT)

143. Counterclaimants incorporate by reference paragraphs 1 through 142 of their Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to paragraphs 1 through 142.

144. Arbutus and Genevant have sought to enforce and/or license the '098 Patent for products and acts they know are outside the claims of the '098 Patent.

ANSWER: Denied.

145. For any claims directed to flow rates, all family members of the '098 Patent family prior to the filing of the application that resulted in the '098 Patent require mixing an organic lipid solution with an aqueous solution by introducing them into a mixing environment at "substantially equal flow rates" or "about equal flow rates."

ANSWER: The '098 Patent and all patents and patent applications in the '098 Patent family speak for themselves. Plaintiffs deny the remaining allegations in paragraph 145.

146. All Figures in the '098 Patent illustrating flow in the "T-connector" are described as disclosing flow rates that are "substantially equivalent for both lipid and aqueous solution flows."

ANSWER: The '098 Patent speaks for itself. Plaintiffs deny the remaining allegations in paragraph 146.

147. Arbutus only began prosecuting the claims of the '098 Patent, directed to a process for producing a lipid vesicle by mixing an organic lipid solution with an aqueous solution by introducing them into a mixing environment at "different flow rates relative to each other," after CNN aired the interview during which an image of a T-mixer was shown and years after the alleged priority date of the '098 Patent.

ANSWER: Plaintiffs admit that the '755 Application was filed on May 25, 2021. Plaintiffs deny any remaining allegations of paragraph 147.

148. There is no support for the claims of the '098 Patent in its specification.

ANSWER: Denied.

149. Arbutus's and Genevant's conduct in seeking to license and enforce the '098 Patent against products and acts they know to be outside the scope of the claims of the '098 Patent and

outside the scope of what was actually invented is an attempt to seek an improper economic benefit.

ANSWER: Denied.

150. Arbutus and Genevant have engaged in a course of conduct that seeks to broaden the scope of the '098 Patent with anticompetitive effect.

ANSWER: Denied.

151. Arbutus's and Genevant's misuse of the '098 Patent renders it unenforceable.

ANSWER: Denied.

JURY DEMAND

Counterclaimants request a trial by jury on all claims so triable in this action.

ANSWER: Plaintiffs acknowledge that Defendants' Counterclaims purport to set forth a demand for a jury trial on all issues and claims so triable. This paragraph contains conclusions of law to which no response is required. To the extent a response is required, Plaintiffs deny the allegation in this paragraph and deny that Defendants are entitled to any relief whatsoever.

RESPONSE TO RELIEF REQUESTED

ANSWER: Paragraphs (a) through (h) set forth Defendants' requests for relief to which no response is required. To the extent a response is required, Plaintiffs deny that Defendants are entitled to their requested relief, or any relief whatsoever.

To the extent that a further answer is required to any paragraph of Defendants' Counterclaims, Plaintiffs deny all further allegations. Any allegation of Defendants' Counterclaims not expressly admitted herein is denied.

PLAINTIFFS' AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE (FAILURE TO STATE A CLAIM)

Defendants' Counterclaims fail to allege facts sufficient to state a cause of action and fail to state a claim on which relief may be granted.

Plaintiffs reserve the right to assert further affirmative defenses in the event that discovery indicates that such defenses would be appropriate.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

A. An order dismissing each of Defendants' counterclaims, with prejudice, and denying all relief sought by Defendants;

B. A declaration that this is an exceptional case and an award of attorney's fees pursuant to 35 U.S.C. § 285;

C. Costs and expenses in this action; and

D. Such further and other relief as this Court may deem just and proper.

Dated: August 14, 2023

Respectfully submitted,

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